香港申訴專員公署

Office of The Ombudsman, Hong Kong

主動調查報告
Direct Investigation Report

政 府 監 管 私 營 醫 療 機 構 提 供 疫 苗 機 制
Government's Mechanism for Monitoring Vaccines Provided by Private Healthcare Facilities

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1

INTRODUCTION

BACKGROUND

1.1 Advances in medicine have brought us more and more vaccines against diseases such as diphtheria, measles, pneumonia and influenza, as well as the human papillomavirus ("HPV") which has drawn more attention in recent years. In Hong Kong, some vaccines have been included in the Government's Vaccination Schemes and members of the public can receive scheduled vaccinations as they grow up. For vaccines not included in the Schemes, people can make their own arrangements based on their need and wish for vaccination.

1.2 As more and more vaccines against diseases are developed, we also receive more and more vaccinations. The safety and efficacy of vaccines naturally attract much public attention. Because vaccines are either injected or taken orally into the human body, those of defective quality would directly affect or even jeopardise the health of people. Proper monitoring of vaccines by the Government is of paramount importance.

1.3 In mid-2019, there had been media reports that some private healthcare facilities ("PHFs") were providing allegedly defective nine-valent HPV vaccines. The Department of Health ("DH") and the Customs and Excise Department ("C&ED") subsequently took joint actions and uncovered counterfeit HPV vaccines in some PHFs. This had aroused public concern over the effectiveness of the Government's monitoring of vaccines.

1.4 Against this background, The Ombudsman initiated a direct investigation on 20 August 2020 against the Food and Health Bureau ("FHB"), DH and C&ED to examine whether the Government has put in place a proper mechanism for monitoring vaccines provided by PHFs, identify room for improvement, and enhance public understanding of the Government's monitoring efforts.

SCOPE OF INVESTIGATION

1.5 The scope of this direct investigation covers:

- the registration and monitoring mechanism for vaccines in Hong Kong;
- the market surveillance mechanism;

- handling of complaints and reports relating to vaccines by the monitoring authorities;

- the strengthened monitoring measures implemented since 2019; and

- the Government's dissemination of information to the public.

PROCESS OF INVESTIGATION

1.6 In the light of the public concern over the Government's monitoring of vaccines (see **para. 1.3**) and the complaints we received during the period in question, we initiated preliminary inquiries with the relevant departments in August 2019. Having carefully examined the information obtained, we announced the launch of this direct investigation on 20 August 2020 and invited members of the public to give their views on the topic. We also requested relevant information from FHB, DH and C&ED and met with DH's representatives in order to understand further the details of the monitoring mechanism.

1.7 On 7 January 2021, we issued a draft investigation report to FHB, DH and C&ED for comments. Upon considering their comments, we completed this final report on 2 March 2021 and then uploaded it in full to our Office website (www.ombudsman.hk).

2

MONITORING MECHANISM FOR VACCINES

VACCINE REGISTRATION

2.1 In Hong Kong, any product that meets the definition of "pharmaceutical products" under section 2 of the Pharmacy and Poisons Ordinance ("PPO") must satisfy the criteria of safety, efficacy and quality[1] as prescribed in sections 36 and 37 of the Pharmacy and Poisons Regulations ("PPR"). Registration with the Pharmacy and Poisons Board of Hong Kong ("Board") is also required before any such product can be sold or distributed locally. DH's Drug Office is responsible for enforcing the PPO and provides administrative and technical support to the Board. Vaccines are pharmaceutical products defined under section 2 of the PPO. DH's mechanism and measures for monitoring vaccines are no different from those already in place for pharmaceutical products as defined under the PPO.

2.2 For pharmaceutical products (including vaccines) containing new chemicals or biological entities (i.e. active ingredients which have not been registered in Hong Kong), legislative amendment to the PPR is required for incorporating the new chemicals or biological entities in question into the relevant Schedules of the PPR for regulatory control before the products can be registered with the Board. Currently, a "secondary review" approach is adopted in Hong Kong with respect of applications for registration of pharmaceutical products containing new chemicals or biological entities, meaning that approval of applications would be based on the vetting results by approved drug regulatory authorities. Applicants must provide documentary proofs of registration and free sale certificates of the products issued by the drug regulatory authorities of two or more designated reference countries[2], as well as the other documents as set out in the Guidance Notes on Registration of Pharmaceutical Products/Substances promulgated by DH to prove that the products in question meet the criteria of safety, efficacy and quality.

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[1] The applicant for registration of a pharmaceutical product should submit adequate information to the Board to prove that the product concerned meets the criteria of safety, efficacy and quality. The information includes the complete production formula, quality standards, laboratory reports and testing method, manufacturer licence, the PIC/S GMP certificate (i.e. the Good Manufacturing Practice" promulgated by the Pharmaceutical Inspection Co-operation Scheme), free sale certificate issued by the drug regulatory authority of the country of origin, a replica of the sales pack, related scientific information or reference literature and stability tests, etc.

[2] DH's Guidance Notes on Registration of Pharmaceutical Products/Substances lists out 32 approved countries, including Australia, Canada, the EU countries, Japan, Switzerland and the U.S.

2.3 All registered pharmaceutical products in Hong Kong (including vaccines) should carry a Hong Kong registration number on their package in the format of "HK-XXXXX". The website of DH's Drug Office contains information of all pharmaceutical products registered in Hong Kong, including the product names, active ingredients and names of the registered holders, etc. for reference by the public and the trade. The relevant committee under the Board may revoke or suspend the registration of a pharmaceutical product under section 36(8) of the PPR if it considers that doing so is in the public interest (e.g. there is evidence showing that the safety or efficacy of the product is questionable) after scrutinising information or evidence. According to records, the relevant committee had not revoked or suspended the registration of a vaccine or other pharmaceutical products under the section between 2017 and 2019.

WHOLESALE DEALER LICENCE

2.4 In Hong Kong, drug wholesale dealers engaging in the procurement, import and distribution of vaccines must apply for a licence from the Board under sections 25 and 26 of the PPO. Licensed drug wholesale dealers must strictly observe the Board's licensing conditions. In respect of procurement, import, sales records and storage facilities, licensed wholesale dealers must follow the requirements of the Code of Practice for Holder of Wholesale Dealer Licence ("Code of Practice") drawn up by the Board in accordance with section 4B of the PPO.

2.5 The wholesale dealer licence would specify the authorised storage location for the pharmaceutical products of the dealer. If the pharmaceutical products need to be stored elsewhere, prior approval by the Board must be obtained. Storing pharmaceutical products at an unauthorised location would be deemed a violation of the licensing conditions by the licensed wholesale dealer, and the Board may instigate disciplinary action against the dealer in question under the PPR. Between 2017 and 2019, there were no cases involving disciplinary action against licensed wholesale dealers for storing pharmaceutical products at premises other than those authorised in their licences.

MANAGEMENT SYSTEM FOR PROCUREMENT, IMPORT/EXPORT AND STORAGE

2.6 Hong Kong does not have vaccine manufacturers of its own. Local healthcare facilities must, therefore, procure vaccines manufactured by overseas drug manufacturers via licenced drug wholesale dealers. Regarding quality control of vaccines, the usual practice across drug regulatory authorities of various countries is that vaccines produced by drug manufacturers must first go through their local approved quality tests to ensure their meeting the quality criteria before they can be exported to other jurisdictions. On the other hand, Hong Kong has long been an entrepot for all kinds of goods (including pharmaceutical products) and a lot of licensed wholesale dealers are engaged in the import/export of pharmaceutical products. Some

multinational drug manufacturers, using Hong Kong as a transit point, would also first ship their pharmaceutical products here, pending shipment to other Asian markets depending on the demand. Since these pharmaceutical products are not sold in the Hong Kong market, they are not required to register in Hong Kong under the PPO.

2.7 Both the import and export of vaccines and other pharmaceutical products are subject to licensing control under the Import and Export Ordinance ("IEO"). Licensed drug wholesale dealers are required to apply for a licence from DH with respect to each import/export of vaccines, while C&ED is responsible for the enforcement. Licensed drug wholesale dealers must apply for an import licence before importing the products, the quantity of which should not exceed the approved total amount specified in the licence. Upon importation of pharmaceutical products, DH in general would not conduct random checks lest the import of these products and their supply to the market be delayed. This is in line with the practice adopted by international drug regulatory authorities.

2.8 Unregistered pharmaceutical products imported to Hong Kong from overseas countries by licensed drug wholesale dealers for export to other places (i.e. re-export of pharmaceutical products) would generally be stored at the locations authorised in the licence, pending exportation to other markets in batches. An export licence from DH is required prior to every single exportation of pharmaceutical products. The total quantity of products to be exported during a licence's 28-day validity period cannot exceed the quantity approved in the licence. Besides, the dealer must lodge an export declaration regarding the products within 14 days after shipment. Applications for import licences and export licences are handled separately. The management and records of pharmaceutical products are also subject to regulation by the PPO.

2.9 DH and C&ED have established a mechanism in 2002 under which DH would regularly refer a certain number of import/export licences it has issued to C&ED for post-shipment verification for more stringent monitoring of import/export of pharmaceutical products. At present, DH's computer system will select 90 import/export licences[3] in random every week for post-shipment verification by C&ED. Verifications conducted in 2017 and 2018 by C&ED did not find any contravention in relation to the import and export of vaccines. Five cases of contravention of the IEO involving vaccines had been found in the post-shipment verifications conducted in 2019.

2.10 If pharmaceutical products (including vaccines) involve the use of forged trade marks (i.e. counterfeit) or false trade descriptions, C&ED would investigate and prosecute in accordance with the Trade Descriptions Ordinance ("TDO").

2.11 Regarding storage, most vaccines must be kept in a cold storage or refrigerator at a temperature between 2°C to 8°C. In vetting applications for a drug wholesale dealer licence, the Board would make reference to the Code of Practice to decide whether the premises of the applicant has a proper storage facility. Licence

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[3] Including 40 licences involving registered or unregistered drugs supplied to medical practitioners, dentists and veterinary surgeons, and 50 licences involving unregistered pharmaceutical products for re-export.

applicants and holders must regularly monitor the temperature and condition of their storage facilities, and make advance contingency planning for potential risks and challenges (such as power disruption). Licenced drug wholesale dealers must also ensure that vaccines are kept at a proper temperature in a suitable environment during transportation, and procure and import vaccines from reputable drug manufacturers.

MONITORING PHARMACEUTICAL PRODUCTS

2.12 FHB pointed out that the most important and effective part of the international drug regulatory strategy is to ensure the quality of pharmaceutical products through the drug manufacturers' quality assurance system. Drug manufacturers must strictly conform with the Good Manufacturing Practice ("GMP") drawn up for drugs. The quality assurance system aims at providing quality guarantee for pharmaceutical products through personnel training, setting standards for the workshop and manufacturing equipment, requirements in respect of manufacturing and packaging materials, verification for manufacturing procedures and inspections, requirements on documentation, verification of contractors, as well as post-production arrangements, etc.

2.13 Since January 2016, the Board has become a member of the Pharmaceutical Inspection Co-operation Scheme ("PIC/S") and adopted more or less the same mode of monitoring regarding pharmaceutical products as other member authorities, such as the U.S. Food and Drug Administration, the Medicines & Healthcare Products Regulatory Agency of the United Kingdom, and the Therapeutic Goods Administration of Australia. The Board and the other PIC/S member authorities require all drug manufacturers under their jurisdictions who sell or distribute pharmaceutical products (including locally produced and imported ones) to comply with the PIC/S GMP.

2.14 The notification mechanism of the PIC/S allows close liaison between DH and the drug regulatory authorities of other countries and regions. If a member authority detects possible safety, efficacy and quality hazards in a pharmaceutical product, or that a drug manufacturer has violated the GMP, it will promptly notify other affected member authorities for follow-up actions. DH would continue to watch closely the latest situation and development in the international scene with respect to regulation of pharmaceutical products.

DH's MARKET SURVEILLANCE MECHANISM

2.15 DH has established a regular risk-based market surveillance mechanism to collect pharmaceutical products from drug suppliers and the market for test in order to monitor the safety, efficacy and quality of such products, as well as situations which may compromise the quality of vaccines during transportation and storage[4]. The risk

[4] The PPO has not authorised Health Inspectors to enter or inspect the premises of registered medical practitioners or registered dentists. DH's regular surveillance mechanism (including taking samples of pharmaceutical products from suppliers and the market for test), therefore, does not cover the clinics of

assessment criteria and factors of consideration cover the following two aspects:

(1) the intrinsic risks of pharmaceutical products, such as whether the products contain multiple active ingredients, and whether the ingredients are relatively unstable or easily degradable; and

(2) the extrinsic risks of pharmaceutical products, such as whether the products have been found to be defective or possibly defective, and whether the drug manufacturer concerned has any previous record of violating the GMP.

2.16 Based on the PIC/S notification mechanism, information disseminated by overseas regulatory authorities, as well as complaints and inquiries lodged by local drug suppliers or healthcare professionals, DH conducts risk assessments and determines the arrangements for sampling of pharmaceutical products in the market. Should sampling tests on vaccines be necessary, the tests would focus on visible foreign materials, chemical composition, metallic contamination and sterility. Between 2017 and 2019, DH had conducted tests on 137 doses of vaccines (in nine batches) from the market in 2018 in accordance with the above risk assessment criteria and factors of consideration.

DH's PROCEDURES FOR FOLLOWING-UP ON NON-COMPLIANT PHARMACEUTICAL PRODUCTS AND PENALTY

2.17 If DH finds that any pharmaceutical products (including vaccines) might be non-compliant with the safety, efficacy and quality criteria or other related requirements, or if it receives complaints about pharmaceutical products, it would immediately launch an investigation in accordance with the PPO. In addition, pharmaceutical products that are found to be defective and need total recall from the market would be placed on DH's surveillance list and put to sampling tests upon the next importation. DH may conduct laboratory tests on pharmaceutical products in the course of investigation. Where necessary, it would take joint enforcement actions with other departments, seek legal advice from the Department of Justice ("DoJ") and instigate prosecution upon sufficient evidence. Depending on the nature of a case, offences possibly in breach of the relevant ordinances in general include:

(1) illegal possession of Part 1 poisons, or illegal possession/sale of unregistered pharmaceutical products contravenes respectively the PPO and the PPR. Upon conviction, the maximum penalty for each offence is a fine at level 6 ($100,000) and two years' imprisonment; and

(2) selling a drug which is not of the quality of the drug demanded by the purchaser (e.g. selling expired drugs or drugs that are tested and confirmed to be defective) is in breach of section 52 of the Public Health

registered medical practitioners or registered dentists.

and Municipal Services Ordinance ("PHMSO"). Upon conviction, the maximum penalty is a fine at level 3 ($10,000) and three months' imprisonment.

Between 2017 and 2019, DH had instigated one prosecution in 2019 for each violation of the above two pieces of legislation with respect to vaccines. In both cases, the persons involved were convicted in 2020.

2.18 In serious public health incidents, DH would publish relevant information in a timely manner and may request the supplier(s) to recall the problematic products. Public announcement would be made on the Department's website or through press releases.

DH's INSPECTIONS AND ENFORCEMENT

2.19 DH has established a mechanism for conducting inspections on licensed drug wholesale dealers. The annual routine inspections of some 700 licensed dealers in Hong Kong cover the import/export and sale documents, records, labels of the registered pharmaceutical products, quantity and storage of pharmaceutical products, the dealers' mechanism for handling recalled products and compliance with the Code of Practice. Detailed records on the items inspected and assessment results would be made after each inspection.

2.20 DH also acts on complaints and intelligence to conduct extra and special inspections on licensed drug wholesale dealers where warranted. During special inspections, DH officers would check whether the wholesale dealers' import/export documents match the details in the import/export licence, and whether the transaction records and stock and storage of vaccines satisfy the requirements of the PPO, PPR and their licences. Between 2017 and 2019, DH conducted 2 and 26 special inspections on licensed wholesale dealers in 2018 and 2019 respectively upon receipt of complaints and intelligence relating to vaccines.

2.21 Licence holders would not be notified prior to inspections. DH would take follow-up actions if illegal activities or non-compliance with the Code of Practice are found during inspections. Cases involving conviction or non-compliance with the Code of Practice would be referred to the Pharmacy and Poisons (Wholesale Licence) Committee ("Committee"), set up by the Board in accordance with section 26 of the PPR, for deliberating disciplinary action. The verdicts made by the Committee may include a decision to revoke a wholesale dealer's licence, suspend his licence for a period specified, issue a warning letter to the licensed wholesale dealer involved, or alter the licencing conditions imposed on that wholesale dealer. Between 2017 and 2019, the disciplinary actions taken against non-compliant licensed wholesale dealers included issuance of 28 warning letters and suspension of licence in 7 cases. None of the cases involved vaccines.

2.22 According to section 35 of the PPO, the Chairman of the Board may authorise in writing any public officer to be an inspector for the purpose of the PPO. For the purpose of enforcing the provisions of the PPO, an inspector thus authorised shall have the power to conduct inspections and investigations, including "to seize and detain any article, document or thing which appears to him to be or to contain evidence of an offence against the Ordinance; and to make such examination and inquiry and to do such other things, including the taking, on payment therefor, of samples, as may be necessary for the purposes of the inspection". Public officers of DH authorised in accordance with the PPO to act as inspectors shall, according to section 28 of the PPR, inspect the records kept by licensed wholesale dealers and, where necessary, seize the records for further investigation. Nevertheless, the PPO does not authorise DH to seize the transaction records of licensed wholesale dealers (including the names of those supplied with the pharmaceutical products) and disclose the information to the public. Of the inspections conducted in 2017, 2018 and 2019 against licensed wholesale dealers, 11, 10 and 33 inspections respectively involved the examination of records relating to vaccines. In one inspection in 2019, the authorised officer had seized the records for further investigation.

C&ED's VERIFICATIONS AND ENFORCEMENT

2.23 Upon importation/exportation of vaccines, C&ED would conduct clearance examinations according to the risk management principle in order to ensure compliance with the IEO by importers/exporters. During clearance examinations, C&ED officers would check whether the goods match the descriptions on relevant documents, including descriptions on the external packaging, import/export licences, cargo manifest, bill of lading, invoice, etc. Under section 6C (1) of the IEO, importation of vaccines is subject to obtaining an import/export licence [5] issued by DH and compliance with the requirements specified in the licence. C&ED would conduct follow-up investigation if it discovers during clearance examinations that a certain batch of vaccines does not match the descriptions on the import licence or no licence is attached to the vaccines.

2.24 Under the established mechanism, DH will select in random a certain number of import/export licences it issued and refer them to C&ED for post-shipment verification (see **para. 2.9**) to ensure that the movement of the vaccines complies with the licence requirements. On receiving DH's referral, C&ED would conduct surprise post-shipment verification at the premises registered on the import/export licences by the importer/exporter. If the premises location has changed, C&ED would conduct verification at the new premises and notify DH in a timely manner for follow-up action. Between 2017 and 2019, C&ED had handled one case in 2019 in which its officers had to conduct the post-shipment verification at another premises because the registered premises location on the import/export licence had changed.

[5] Section 3 of the IEO stipulates that the Director-General of Trade and Industry may issue any licence required under the Ordinance. The Director-General has delegated the power and duty to issue import/export licences for pharmaceutical products to the officers designated by DH.

2.25 In the course of verification, C&ED officers would request importers/exporters to produce licence-related documents, such as contracts, invoices, packing lists, bills of lading, etc for verifying whether the goods match the descriptions as claimed in the licences. In addition, they would follow up on the status of vaccines. If the vaccines are already re-exported overseas, the officers would check the relevant re-export documents; if they are still sitting at the premises of the importer/exporter, C&ED officers would check on-site at once the relevant information, including product names, quantity and batch numbers, etc to confirm their matching the information provided by the importer/exporter. C&ED would also ask the importer to provide the expected date of exportation and follow up on the vaccines until all of them have been exported. If there is a discrepancy between the import/export information and the information declared, C&ED would take immediate actions to identify violations of the IEO, if any. Since there are stringent requirements regarding the storage environment of vaccines, C&ED officers would not open the packaging to examine the vaccines during verification.

2.26 According to section 12(1) of the TDO, the importation/exportation of counterfeit vaccines or vaccines with a false trade description is an offence; while section 7(2) of the TDO stipulates that any person who in the course of any trade or business applies a false trade description to any vaccines, supplies or offers to supply any vaccines to which a false trade description is applied, or has in his possession for sale or for any purpose of trade or manufacture any vaccines to which a false trade description is applied commits an offence. It is also an offence under section 9(2) of the TDO for any person to sell or expose or have in his possession for sale or for any purpose of trade such vaccines. Between 2017 and 2019, C&ED had instigated prosecution in three cases involving vaccines in breach of the TDO in 2019.

2.27 C&ED pointed out that monitoring the quality of vaccines is not within its purview, and the Consumer Goods Safety Ordinance, enforced by the Department, only regulates general consumer goods available in the market and does not cover pharmaceutical products, including vaccines. C&ED, therefore, would not conduct random sampling checks or laboratory tests for vaccines imported and supplied to the market, or those provided to private clinics for vaccination by members of the public.

2.28 Any person violating the aforementioned provisions of the IEO is, upon conviction, liable to a maximum penalty of a fine of $500,000 and two years' imprisonment. For violation of the TDO requirements, the maximum penalty would be a fine of $500,000 and five years' imprisonment on conviction.

2.29 Upon receipt of report about violation of the IEO or TDO, C&ED would launch a criminal investigation to probe the background of the case, meet with the persons involved, conduct searches at the premises in question, collect documentary evidence and seize suspicious articles (including defective vaccines), etc. On sufficient evidence, C&ED would instigate prosecutions against the importer, wholesale dealer, clinic, medical centre and other offenders. Investigations into reports of counterfeit vaccines would entail C&ED's seeking assistance from the trade mark holder

to verify the authenticity of the vaccines.

2.30 When a case is cracked, C&ED would publicise the course of its operations through the media to remind the public to be wary of the products or services in question, so long as such disclosure does not compromise its prosecution work in future.

MONITORING MECHANISM FOR HANDLING OF DRUGS BY PHFs

2.31 At the time of the incidents involving nine-valent HPV vaccines (see **para. 1.3**), all PHFs (including medical consulting rooms of registered medical practitioners) other than medical clinics under the purview of the Medical Clinics Ordinance and private hospitals/nursing homes overseen by the Hospital, Nursing Homes and Maternity Homes Registration Ordinance were not subject to DH's monitoring or licensing control. DH did not have the statutory authority to conduct routine inspections on those facilities or premises.

2.32 Section 35(2) (b) of the PPO stipulates that an inspector authorised by DH has the power to enter and conduct investigation at a premises where he has reason to suspect that an offence under the Ordinance is being or has been committed. Nevertheless, section 35(5) of the PPO prescribes that other than those premises where the dispensing, manufacturing or compounding of pharmaceutical products are carried out, DH officers are not authorised to enter or inspect the premises of registered medical practitioners, registered dentists or registered veterinary surgeons. Generally speaking, when DH receives a complaint about registered medical practitioner having dispensed problematic drugs, it would investigate and follow up on the complaint in accordance with the PPO and the PHMSO. If in the course of complaint-handling or investigation DH finds that the incident may involve violation of other laws which DH has no authority to enforce, it would refer the case to the relevant enforcement department for follow-up or take joint action with the department where warranted.

2.33 FHB explained that the Private Healthcare Facilities Ordinance ("PHFO") enacted by the Legislative Council ("LegCo") in 2018 adopts a "premises-based approach" to monitor the premises of registered medical practitioners and registered dentists for stricter regulation of all PHFs[6]. In future, clinics providing vaccination services to patients must apply for a licence or an exemption in accordance with the PHFO, which stipulates that licenced clinics (excluding small practice clinics with valid exemption) must comply with the requirements of the relevant code of practice. Paragraph 3.4.1 of the relevant draft code of practice provides that the chief medical executive of a clinic must ensure that the handling and supply procedures of drugs comply with the relevant Hong Kong laws as well as the prevailing guidelines promulgated by the relevant regulatory authorities. DH has the power to inspect licensed clinics and take regulatory actions (including revoking the clinic's licence)

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[6] DH is implementing the PHFO in phrases in order to replace the Hospital, Nursing Homes and Maternity Homes Registration Ordinance as well as the Medical Clinics Ordinance. Under the PHFO, there are four types of PHFs, namely hospitals, day procedure centres, clinics and health services establishments.

upon confirmed violation of the code of practice. For small practice clinics granted an exemption from licence application under section 41 of the PHFO, the Director of Health has been empowered by the Ordinance to revoke an exemption if he considers a clinic has operated in a way contrary to the public interest. FHB will announce the arrangements for applications for clinic licence and exemption under the PHFO.

REGISTRATION AND DISCIPLINARY REGULATION SYSTEM REGARDING REGISTERED MEDICAL PRACTITIONERS

2.34 The Medical Council of Hong Kong ("MCHK") is empowered by the Medical Registration Ordinance and its subsidiary legislation – the Medical Practitioners (Registration and Disciplinary Procedure) Regulation to handle matters relating to the registration and disciplinary regulation of medical practitioners in Hong Kong. Registered medical practitioners must also comply with other relevant laws and observe the Code of Professional Conduct ("Code of Conduct") drawn up by the MCHK to render safe and up-to-standard medical services (including vaccination services). Registered medical practitioners who violate the Code of Conduct may face disciplinary action by the MCHK. The Council would handle complaints about registered medical practitioners in accordance with its statutory powers and established procedures.

2.35 The vaccines listed in Schedule 3 to the PPR (including HPV vaccines and other vaccines for ordinary human use) are "poisons", to be supplied or sold only as per prescriptions by registered medical practitioners, registered dentists or registered veterinary surgeons. Anyone who supplies or sell poisons listed in Schedule 3 without a prescription by a registered medical practitioner commits an offence and is liable to a fine at level 6 ($100,000) and two years' imprisonment. Between 2017 and 2019, DH had handled 17 cases involving conviction of supplying drugs without authorisation by a doctor's prescription. No vaccines were involved.

2.36 Drugs (including vaccines) can be administered by a registered medical practitioner or by another eligible authorised person under his supervision. If the drug is not administered by a registered medical practitioner or under the supervision of a registered medical practitioner, the administrator may be practising medicine without registration and contravene section 28 of the Medical Registration Ordinance. This is an offence liable on conviction to imprisonment for seven years maximum. The Ordinance is enforced by the Police. Upon receipt of a complaint about pharmaceutical products (including vaccines) which involves or is found during investigation to involve practising medicine without registration, DH would refer the case to the Police for follow-up, and may take joint action with the Police where warranted. Between 2017 and 2019, DH had referred to the Police/assisted in Police investigation in three cases relating to vaccination services and allegedly involving practising medicine without registration.

ENSURING SUPPLY OF VACCINES AND PUBLIC EDUCATION

2.37 There are only limited vaccine manufacturers in the world and the supply of vaccines is affected by a host of factors, including problems in the production lines, outbreaks of epidemic in different places and the vaccine policies of different governments, etc. In Hong Kong, DH's Vaccination Schemes already covers the majority of vaccines for human use. Consequently, the Government would, via contracts, require vaccine suppliers to provide sufficient quantity of vaccines. DH also stays in close liaison with healthcare professionals and drug suppliers to ensure a stable supply of vaccines to Hong Kong including the private market. After deliberations with local suppliers, DH has since January 2018 started to require them to alert DH in advance should there be a possible shortage in the supply of important drugs (including vaccines), so that DH can introduce corresponding measures and seek to import the drugs involved from other sources.

2.38 DH's Drug Office has set up a webpage dedicated to "Vaccination" on its website for educating the public on knowledge about vaccination and how to tell whether a vaccine has been registered or not. Members of the public can look up information about the registration certificate holders of individual pharmaceutical products and verify with the Drug Office the registered information of the products in question. People who have queries about the supply of vaccines can seek help from the Drug Office or enquire of the relevant drug manufacturers.

3

HANDLING COMPLAINTS AND REPORTS

COMPLAINTS ABOUT NINE-VALENT HPV VACCINES RECEIVED BY DH AND C&ED

3.1 HPV vaccine is a prophylactic vaccine to prevent cervical cancer as well as other HPV-related cancers or diseases. In Hong Kong, HPV-16, 18, 31, 33, 45, 52, 58 accounted for about 90% of cases of cervical cancer. All the above seven genotypes are included in the nine-valent HPV vaccine.

3.2 Between the registration of the nine-valent HPV vaccine in Hong Kong in December 2015 and December 2018, DH had received around 50 complaints relating to the vaccine. Since 2017, DH has been in touch with the supplier of the nine-valent HPV vaccine and the MCHK regarding the supply of the vaccine, which became tight in 2018. That year, DH received four reports from the supplier who suspected there were illegally supplied or unregistered nine-valent HPV vaccines in the market. Investigation into those four cases found no unregistered nine-valent HPV vaccines.

3.3 Between January and April 2019, DH received in total only 11 complaints about nine-valent HPV vaccines. The number of complaints, however, began to soar in May: between that month and August, DH received as many as 1,875 reports about the vaccine. Most of those cases involved PHFs allegedly providing unregistered parallel imported[7] nine-valent HPV vaccines. Media reports claimed that most of the customers affected are Mainland travellers. The number of complaints DH received each month in 2019 is shown in **Figure 1** below.

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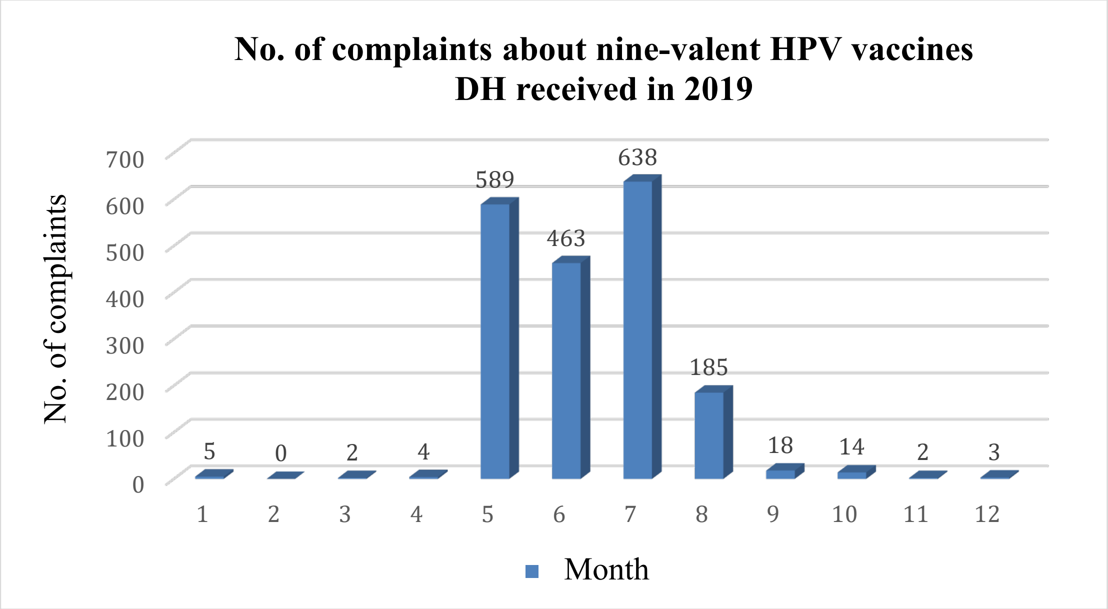
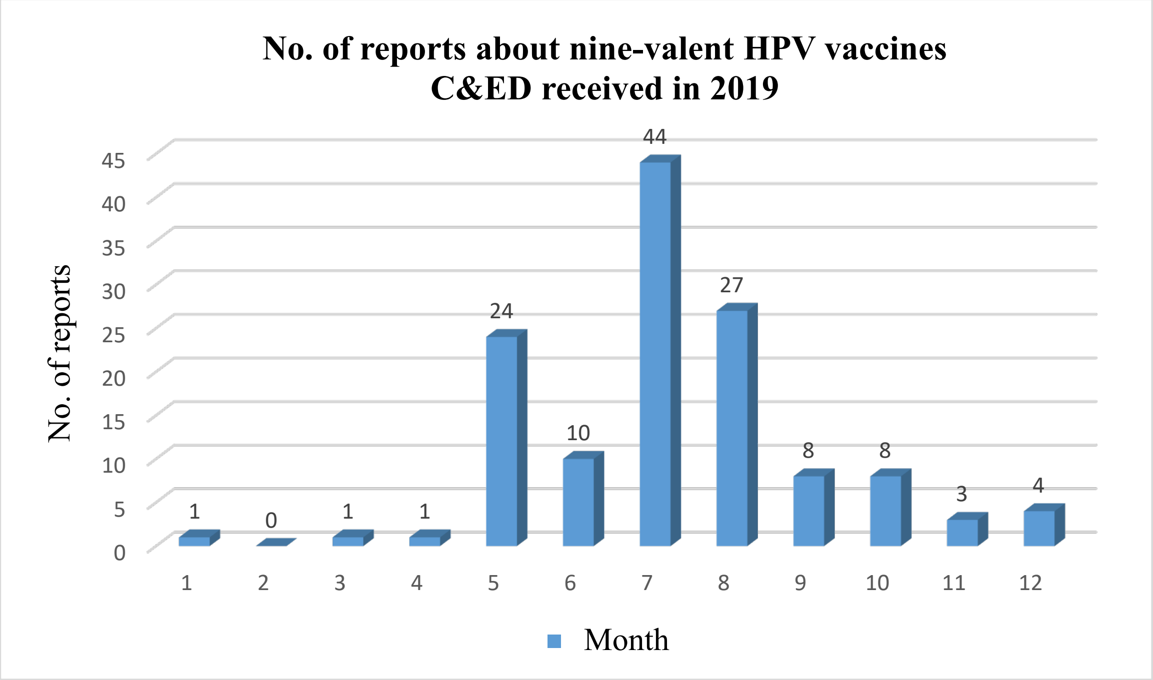
[7] While parallel imported vaccines are manufactured legally by overseas drug manufacturers, their import was not authorized by the registration holder. Their packaging and labels may also look different from registered products.



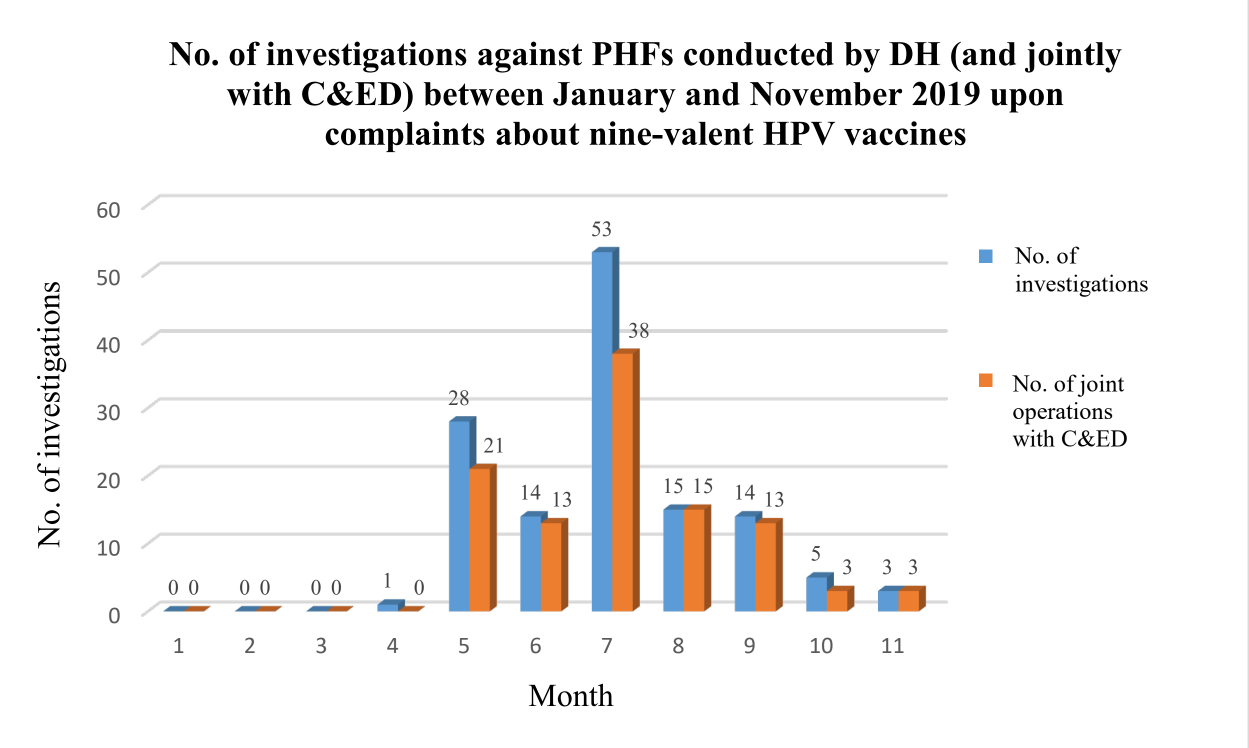
3.4 There was a similar trend in the number of reports relating to nine-valent HPV vaccines received by C&ED in 2019. This is shown in **Figure 2**.



HANDLING COMPLAINTS ABOUT NINE-VALENT HPV VACCINES BY DH AND C&ED

3.5 DH explained that the complaints revealed that Mainland travellers mainly went to some 30 clinics or healthcare facilities in Hong Kong to get the HPV vaccination. Based on the information about the healthcare facilities provided by the complainants, DH officers followed up and analysed each case with sufficient information. Where necessary and with the complainant's consent, DH would refer the case to the relevant

enforcement department for follow-up. Between January and November 2019, DH had conducted 133 inspections or investigations[8] at PHFs in various districts of Hong Kong in the course of following up on the complaints. Most of those inspections or investigations were joint operations with C&ED. The number of operations by month is shown in **Figure 3** below.



3.6 Between May and September 2019, joint operations by DH and C&ED had uncovered several cases involving allegedly counterfeit or unregistered nine-valent HPV vaccines being provided in Hong Kong. Details are in **paragraphs 3.8 to 3.12** below.

3.7 Between 1 January and 8 May 2019, C&ED received nine reports about parallel imported HPV vaccines (which might involve illegally imported vaccines and/or vaccines in breach of import/export licence requirements) and two other reports relating to both parallel imported and counterfeit HPV vaccines. Five medical centres were involved. Since public health was at stake, C&ED accorded priority to these reports, analysed the subject matters and collected relevant information. Upon assessment, C&ED considered evidence to be insufficient for initiating investigation in two of the cases. For the remaining cases, C&ED and DH conducted joint raids at the medical centres in question, but did not find any irregularities.

3.8 On 9 May 2019, C&ED received a report alleging that a medical centre had illegally imported HPV vaccines. It conducted a joint raid at once with DH on 10 May at the medical centre in question and tracked down its two directors, who were eventually arrested on 4 June. They were suspected of violating licence requirements in that they had illegally supplied to the local market unregistered HPV vaccines

[8] A single premises might be the target of several inspections or investigations.

originally intended for re-export. C&ED issued a press release on the joint operation regarding the case on 5 June (see **Annex 1**).

3.9 C&ED had invited the registered trade mark holder of the world's only manufacturer of nine-valent HPV vaccine to engage an expert to help verify the authenticity of the HPV vaccines uncovered during the investigation. On 4 July 2019, C&ED received two referrals from DH, alleging that two medical centres were providing suspected counterfeit HPV vaccines. On 10 July, the two departments conducted a joint raid at those two medical centres and uncovered for the first time counterfeit nine-valent HPV vaccines in Hong Kong. The departments found 76 packs of suspected counterfeit HPV vaccines at one medical centre in Kwun Tong. Two persons were arrested. On 12 July, C&ED and DH held a joint press conference to give a briefing about the operation (**Annex 2**) to remind the public to be more alert to counterfeit HPV vaccines.

3.10 On 12 July 2019, C&ED and DH conducted another joint operation to raid a medical centre in Tsim Sha Tsui and seized 162 packs of suspected counterfeit nine-valent HPV vaccines. A director and two staff members of the medical centre were arrested on suspected violation of the TDO (see relevant press release at **Annex 3**).

3.11 C&ED subsequently received more referrals from DH involving other medical centres allegedly providing counterfeit or illegally imported HPV vaccines. Between 11 July and 12 September, C&ED and DH conducted raids at some 30 medical centres and the premises of two drug importers/exporters. During the raids, C&ED seized the suspected counterfeit HPV vaccines abovementioned and nine doses of HPV vaccines suspected to have applied false trade descriptions at two other medical centres. Seven people were arrested, including the three people arrested on the 12 July operation. In addition, C&ED also cracked two other cases involving allegedly illegal importation/exportation of HPV vaccines. Four people were arrested.

3.12 In the above operations, C&ED had cracked four and three cases involving suspected violation of the TDO and the IEO respectively, arresting 15 people in total. Samples of the HPV vaccines seized in the operations had been sent to laboratories for testing. Upon completion of investigation, C&ED had instituted prosecutions in three cases involving violation of the TDO, and one case involving violation of the IEO.

3.13 Save for the above four cases cracked in July 2019, C&ED had never handled other cases that involved counterfeit HPV vaccines or HPV vaccines with false trade descriptions.

3.14 C&ED undertook to continue to keep a close watch on the situation concerning HPV vaccines that are allegedly illegally imported/exported, counterfeits or using false trade descriptions. It would conduct joint operations with DH where necessary.

RESULTS OF LABORATORY TESTING OF VACCINES SEIZED

3.15 Samples of the suspected counterfeit nine-valent HPV vaccines seized in the joint operations on 10 and 12 July 2019 had been sent to the Government Laboratory and other accredited laboratories for chemical analysis. DH announced the test results on 24 July and 7 August 2019. While no hazardous impurities were detected, no active HPV vaccine ingredients were found in the samples either. One sample was confirmed to contain sodium and chloride, which are commonly found in saline solution. Another alarming finding was that the sample also flunked the sterility test, meaning that it might have been contaminated by microbes and might pose a threat to the person administered the product. DH and C&ED would follow up on prosecution action in accordance with DoJ's advice.

4

STRENGTHENED MONITORING OF NINE-VALENT HPV VACCINES

FACTORS BEHIND BREACHES INVOLVING NINE-VALENT HPV VACCINES

4.1 Risk assessments by DH and C&ED concluded that the chief factors contributing to the 2019 incidents involving nine-valent HPV vaccines are:

(1) the acute increase in demand for the nine-valent HPV vaccine might probably be attributed to the huge number of Mainland travellers who chose to come to Hong Kong for inoculation. Local suppliers of the vaccine could hardly satisfy at once such a great demand in the market;

(2) some licensed drug wholesale dealers, in response to the great demand, might have supplied the local market with parallel imported nine-valent HPV vaccines instead; and

(3) some criminals put counterfeit nine-valent HPV vaccines on the local market.

4.2 DH further explained that the following characteristics of the HPV vaccine have rendered it more prone to parallel imports and counterfeit than other vaccines:

(1) there is only one supplier of nine-valent HPV vaccines in the world, while other vaccines may come from several manufacturers and suppliers;

(2) vaccines in general aim at preventing infectious diseases; but the HPV vaccine can prevent cancers caused by the human papillomavirus; and

(3) the nine-valent HPV vaccine is a newly developed vaccine against cancer. Governments in different jurisdictions are gradually including the HPV vaccine into their vaccination policies. In Hong Kong, the vaccine has since 2020 been included in the Hong Kong Childhood

Immunisation Programme, which offers free vaccination to eligible students. Under such circumstances, the global supply of nine-valent HPV vaccines has always been tight.

STRENGTHENED MEASURES FOR MONITORING NINE-VALENT HPV VACCINES

4.3 DH indicated that in response to the aforementioned incidents involving nine-valent HPV vaccines, DH and C&ED have strengthened the communication mechanism between them, including designating a liaison officer in both departments for notifying and coordinating relevant enforcement actions, conducting risk assessments and deliberating monitoring strategies.

4.4 DH and C&ED have implemented the following measures to strengthen the monitoring of the vaccine to minimise the risk of recurrence of similar incidents:

(1) Starting May 2019, DH would conduct **special inspections** on licensed drug wholesale dealers who have imported unregistered nine-valent HPV vaccines for the purpose of re-export, in order to check whether their import/export documents and bills match the descriptions in the import/export licences, and whether their transaction records, quantity in stock and storage of vaccines comply with the requirements of the PPR and the licences. DH will conduct in-depth investigations into suspicious import/export cases.

In 2019, DH had conducted 25 special inspections or investigations, including three joint operations with other departments. The special inspections found that the licensed wholesale dealers had exported the HPV vaccines mainly to the Mainland, India, Macao and Cambodia, etc. In general, the import/export documents inspected were found to have complied with relevant requirements.

(2) From May 2019, based on the supply situation of the nine-valent HPV vaccine, the complaints received and its surveillance on publicity about the vaccination services, DH **took the initiative to investigate suspicious PHFs**. The number of inspections at PHFs by DH and C&ED is shown in **Figure 3** under **paragraph 3.5** in **Chapter 3**.

(3) Starting 18 July 2019, DH would **refer all** import/export licences it has issued regarding unregistered nine-valent HPV vaccines **to C&ED for post-shipment verification**. Between August 2019 and July 2020, C&ED had conducted 225 post-shipment verifications.

(4) Starting 29 July 2019, C&ED would follow DH's risk assessment and conduct **pre-licensing verification** on individual applications for

import/export licences of the vaccine. It would also adopt **special clearance procedures** for all import/export cases involving unregistered nine-valent HPV vaccines to verify the information and quantity of the vaccines before they are imported/exported. Between August 2019 and July 2020, C&ED had conducted pre-licensing verification on one application for import/export licence, and clearance examination on 14 batches of nine-valent HPV vaccines.

(5) Starting 29 July 2019, wholesale dealers must submit written application to DH in respect of import/export licences for unregistered nine-valent HPV vaccines, instead of submitting electronic applications via the Pharmaceuticals License Application and Movement Monitoring System. The applicants **must also submit documentary proofs such as photographs and information of the products**. DH would refer the applications and the documentary proofs to C&ED for verification before issuing an import/export licence to the wholesale dealer;

(6) DH had discussed with the wholesale dealers of nine-valent HPV vaccines the **use of latest logistics tracking technology** to facilitate identification and tracking of vaccines or similar drugs in the long run. This would help DH, drug suppliers and healthcare professionals to differentiate authentic products and combat unregistered and counterfeit drugs more effectively. According to the information provided by the vaccine manufacturer, it has already been using blockchain technology since April 2020 to store data about the supply chain of nine-valent HPV vaccines safely in its database. Members of the public, the relevant sector and healthcare professionals can use the eZTracker mobile phone application to scan the QR code on the packaging of the nine-valent vaccine to verify whether a specific pack of vaccine is imported and supplied by an authorised dealer. Since the blockchain platform has been linked to the information covering the release, distribution, supply, inspection and acceptance of the vaccines, unregistered or counterfeit drugs cannot apply or imitate the technology. This can help protect the rights of the purchasers and patients;

(7) DH had **issued a letter to healthcare professionals** on 30 May 2019, reminding them that they must procure registered pharmaceutical products for treatment purpose from licensed drug suppliers; and

(8) DH had **contacted the Consumer Council** ("CC") in mid-2019 **to discuss publicity measures targeting Mainland travellers who come to Hong Kong for medical treatment** in a bid to help them understand from the perspective of consumers Hong Kong's control on drugs and choose service suppliers offering more protection. At DH's request, CC has once included a link to the Department's "Vaccination"

webpage (see **para. 2.38**) on its own "Smart Shopping in Hong Kong" （精明消費香港遊）webpage (See **Annex 4**), which gives travellers a better idea on the vaccines available in Hong Kong, how vaccines are monitored here and the rights of consumers who receive vaccinations. DH, together with CC, would continue to heed latest developments and coordinate with the Mainland authorities to promote public education in a timely manner.

4.5 As aforementioned, owing to their characteristics, HPV vaccines are more prone to parallel imports or counterfeits than other vaccines (see **para. 4.2**). Upon risk assessment, the strengthened monitoring measures target only nine-valent HPV vaccines, but not other vaccines for the time being. DH would keep a close watch on the supply situation of all kinds of vaccines (especially newly introduced vaccines), conduct risk assessments from time to time, and consider strengthening the monitoring of individual vaccines where warranted.

4.6 C&ED indicated that it would closely liaise with DH. Based on DH's monitoring measures drawn up for various vaccines and its own risk management principle, C&ED would adopt clearance procedures as appropriate according to the established mechanism.

DISSEMINATING INFORMATION ABOUT STRENGTHENED MONITORING MEASURES

4.7 The Government had announced via the following means about the introduction of strengthened measures for monitoring HPV vaccines:

(1) the Secretary for Food and Health, in her reply to a question by a member of the LegCo on 29 May 2019, indicated that the strengthened measures included stepping up inspections, conducting joint operations with other law enforcement departments, enhancing public education and publicity, and maintaining close liaison with the drug manufacturer/supplier about the supply of nine-valent HPV vaccines in Hong Kong.

(2) the Director of Health indicated at a meeting of the Panel on Health Services of the LegCo on 21 October 2019 that DH had stepped up inspections to curb the import/export and use of unregistered nine-valent HPV vaccines; liaised with the licensed vaccine suppliers on the adoption of track-and-trace technology; and provided C&ED with information on import/export licences of nine-valent HPV vaccine to facilitate post shipment verifications. Besides, DH had reminded healthcare professionals that they should procure registered pharmaceutical products from licensed suppliers only. It had also discussed with CC promotion and publicity targeted at consumers.

(3) DH had held briefings for licensed wholesale dealers to explain the new measures for monitoring import/export of unregistered nine-valent HPV vaccines and relevant enforcement details before implementation of the measures in July 2019.

5

Our Comments and Recommendations

OVERALL COMMENTS

5.1 Our investigation revealed that for those vaccines that are in general less prone to parallel imports or counterfeits, the Government has already put in place a quite comprehensive monitoring mechanism with gatekeeping measures at various levels to ensure the safety and quality of the vaccines provided by PHFs. The measures include:

(1) the PPO and PPR stipulate that all vaccines must be registered with the Board before being sold or distributed in the territory. This is to ensure that all vaccines meet the prescribed criteria of safety, efficacy and quality (see **paras. 2.1 – 2.3**);

(2) drug wholesale dealers engaged in the import and distribution of vaccines must be holders of the licence issued by the Board and strictly observe the licencing conditions and the Code of Practice to ensure proper handling of vaccines (see **paras. 2.4 and 2.5**);

(3) in Hong Kong, the import and export of vaccines are regulated by the IEO. Licensed wholesale dealers must apply to DH for licences for importing/exporting vaccines and ensure that the vaccines match the descriptions in the licences. C&ED is responsible for enforcement actions such as post-shipment verifications (see **paras. 2.7 – 2.9**);

(4) DH monitors vaccines available in the market in accordance with the PPO and PPR. It also joins forces with C&ED to take enforcement actions and handle complaints/reports according to the IEO and the TDO (see **paras. 2.15 – 2.30**); and

(5) registered medical practitioners who breach the Code of Conduct and provide unsafe or substandard vaccination service would face disciplinary actions by the MCHK (see **para. 2.34**).

5.2 From the number of vaccine-related inspections conducted in 2017 and 2018 (including post-shipment verifications by C&ED (see **para. 2.9**), DH's sampling tests of vaccines from the market (see **para. 2.16**) and its examination of vaccine records

during inspections at the premises of licensed wholesale dealers (see **para. 2.22**)), we can also see that the departments concerned have been taking actions in accordance with the established monitoring mechanism without obvious inadequacies. The relevant data on complaints/reports and enforcement actions (see **paras. 2.5, 2.9, 2.21, 2.26, 2.35, 2.36 and 3.2**) do not reflect apparent problems in the vaccines supplied by PHFs around that period either. Nevertheless, the 2019 incidents involving the nine-valent HPV vaccines showed the Government's mechanism for monitoring vaccines with excessive demand had been inadequate in the past. The inadequacies, as we notice, fall mainly into three areas: (1) the risk assessment factors under DH's market surveillance mechanism do not include the supply and demand of pharmaceutical products in the market (see **para. 2.15**); (2) the laws enforced by DH do not target counterfeit vaccines, and DH has no authority to conduct routine inspections at PHFs (including clinics of registered medical practitioners) solely on the ground of investigating counterfeit vaccines (see **para. 2.31**); and (3) education and publicity targeted at the main groups receiving the vaccination was insufficient and behind time. Supply of the nine-valent HPV vaccines became tight since 2018. Around mid-2018, a lot of Mainland travellers complained that they could not get vaccinated at PHFs despite having made appointments in advance. There were also media reports about the situation. DH, however, did not immediately strengthen monitoring of the nine-valent HPV vaccines provided by PHFs (such as requesting C&ED to conduct more post-shipment verifications on the imported vaccines, and keeping watch on advertisements targeting Mainland travellers who came to Hong Kong for vaccination so as to identify suspicious medical facilities or clinics), or step up publicity and education targeted at the groups taking the vaccination (Mainland travellers in particular). In addition, DH has no authority to conduct routine inspections at the PHFs involved solely for investigating counterfeit vaccines. Criminals then took advantage of the excessive demand in the market to provide parallel imported or counterfeit HPV vaccines. Fortunately, DH and C&ED promptly took actions in the wake of the incidents to conduct multiple inspections and investigations at the PHFs in question. Arrests were made and prosecutions instituted upon collection of sufficient evidence. Strengthened monitoring measures were also introduced at once.

5.3 When complaints involving nine-valent HPV vaccines started to increase significantly in May 2019 (see **Figure 1** under **para. 3.3** and **Figure 2** under **para. 3.4**), DH and C&ED immediately stepped up investigations against PHFs (see **Figure 3** under **para. 3.5**). Between May and September, DH conducted 24.8 investigations and took 20 joint actions with C&ED on average per month and succeeded in raiding several PHFs providing suspected counterfeit or parallel imported nine-valent HPV vaccines. A number of people were arrested. Meanwhile, the two departments also implemented a number of strengthened monitoring measures, including conducting special inspections on those licensed wholesale dealers who had imported unregistered nine-valent HPV vaccines for the purpose of re-export, referring all import/export licences already issued involving unregistered HPV vaccines to C&ED for post-shipment verification, and taking proactive investigations against suspicious PHFs (see **para. 4.4**). The number of reports/complaints about nine-valent HPV vaccines plummeted since, and no further breaches of regulations have been found to date.

5.4 A lot of people who received nine-valent HPV vaccinations in Hong Kong were Mainland residents (see **paras. 3.3 and 4.1(1)**). With fewer Mainland visitors coming to Hong Kong since mid-2019 due to social unrests and the COVID-19 epidemic, the number of people receiving the nine-valent HPV vaccinations in the territory declined drastically since the third quarter of the year. So, the obvious decrease in reports and complaints relating to the vaccine during the period might be attributed to the prevailing circumstances, as much as to the actions taken by DH and C&ED as mentioned in **paragraph 5.3**.

5.5 Overall, we consider that DH and C&ED had conscientiously enforced the relevant legislative requirements and regulations in monitoring vaccines provided by PHFs, only that the mechanism in the past did not include extra and stricter monitoring for expensive vaccines with a tight supply. In the wake of the 2019 incidents involving nine-valent HPV vaccines, both departments had taken timely remedial actions, reviewed the old monitoring mechanism and introduced improvement measures to combat defective vaccines. We urge the authorities to stay alert and conduct reviews on the monitoring mechanism and measures from time to time. While the PHFO does not regulate counterfeit pharmaceutical products in particular, the Ordinance itself and the relevant inspection system can to a certain extent remind licensed clinics that according to the relevant code of practice, they must ensure that the handling and supply procedures of drugs comply with the relevant statutory requirements, and can enhance the overall management standard of PHFs (see **para. 2.33**). If in the course of complaint handling or investigation DH finds that the alleged non-compliance was related to a piece of legislation outside its remit, it may refer the case to the relevant enforcement department for follow-up or take joint actions with that department where warranted. In response to our investigation, DH indicated that the PHFO is being implemented in phases. Private hospital licences and the first batch of day procedure centre licences issued in accordance with the Ordinance have already come into force in January 2021. Details of applications for clinic licences and letters of exemption for small practice clinics will be announced in due course. Upon implementation of the relevant regulatory regime, DH would oversee licensed clinics in accordance with the requirements of the relevant code of practice on drug handling and supply procedures.

5.6 This Office believes that when media reports revealed in mid-2019 that certain PHFs were providing allegedly defective nine-valent HPV vaccines, some people might worry whether the nine-valent HPV vaccines they had received were defective, and even question the Government's mechanism for monitoring vaccines provided by PHFs. They also expected that the Government could provide relevant information for them to know how to protect their own health and rights.

5.7 Nevertheless, neither FHB nor DH took the initiative to explain to the public in detail the Government's mechanism for monitoring vaccines provided by PHFs or the strengthened monitoring measures introduced in response to those incidents (see **paras. 4.3 and 4.4**). Although C&ED and DH had issued press releases on the three joint operations between May and July 2019 (see **paras. 3.8 – 3.10**), they had only briefed

the LegCo twice when Council members raised questions about the strengthened monitoring measures newly introduced, and held briefings for the licensed wholesale dealers directly affected by the new regulatory measures (see **para. 4.7**). The general public had received very limited relevant information directly from the Government. They could only rely on the "Vaccination" webpage in the Drug Office website for general information and knowledge about vaccination. Actually, people receiving vaccination need to know how to protect their own rights (for instance, by knowing how to find out if the vaccines have been registered (see **para. 2.3**) and how to verify the authenticity of the nine-valent HPV vaccines (see **para. 4.4 (6)**)). An informed and alert general public would also render the Government's monitoring and enforcement efforts much more effective. By announcing the results of this direct investigation, we hope to enhance public understanding of the related information, and we urge FHB, DH and C&ED to learn from the experience to improve arrangements for information dissemination.

5.8 COVID-19 affects all people in the world and there has been initial success in developing vaccines against it. Vaccination among the general population is expected to help relieve the epidemic. Recently, some drug manufacturers are already mass-producing the vaccines, and many governments (including that of Hong Kong) have announced their own vaccination programmes. In the early days of rollout, demand for the vaccines will be huge across the globe and in Hong Kong. Information about the supply, safety, efficacy, test results, etc. of the vaccines may appear to be confusing, or may even lead to misunderstanding and doubts of the general public. Furthermore, while Government-arranged vaccination programmes seem to be the main trend globally at present, it is still possible that drug manufacturers may supply the vaccines to the private markets in individual countries. When that happens, there may be legally imported and parallel imported vaccines, or even counterfeit vaccines in the local private market. FHB and DH must ensure transparency of information about the safety, efficacy, etc. of the vaccines, and about the arrangements of the Government's vaccination programme. Besides, they must strengthen the dissemination of accurate information to the public. Should the COVID-19 vaccines become available in the local private market, FHB, DH and C&ED must play the role of gatekeeper properly to ensure that the quality of vaccines taken by members of the public at PHFs meet the standards.

OUR RECOMMENDATIONS

5.9 In the light of the above, The Ombudsman makes the following recommendations to FHB, DH and C&ED:

(1) to keep a close watch on the effectiveness of the newly introduced strengthened monitoring measures, and make adjustments or amendments when necessary (see **paras. 4.4 and 5.5**);

(2) to include a pharmaceutical product's supply and demand in the market

as a risk assessment factor under DH's market surveillance mechanism (see **para. 5.2**);

(3) to review the information dissemination mechanism. Should serious incidents involving pharmaceutical products occur, they should promptly and proactively explain to the general public their monitoring mechanism, actions taken and the monitoring measures to be introduced so as to allay doubts among members of the public (see **para. 5.7**); and

(4) to enhance the transparency of information about vaccines newly introduced and proactively provide the public with information about the safety, efficacy, supply etc of new vaccines in a timely manner so that they can understand how to protect their health and rights (see **para. 5.8**).

RESPONSE FROM DEPARTMENTS

5.10 FHB, DH and C&ED have accepted our investigation report. We are glad to note that the departments have been taking follow-up actions to implement our recommendations gradually.

ACKNOWLEDGEMENTS

5.11 The Ombudsman thanks FHB, DH and C&ED for their positive cooperation during the course of this investigation.

Office of The Ombudsman
Ref: OMB/DI/442
March 2021

Annexes

Annex 1

Hong Kong Customs combats illegal import of pharmaceutical products
****

Hong Kong Customs yesterday (June 4) arrested two directors of a medical diagnostic group suspected of illegally importing pharmaceutical products, in contravention of the Import and Export Ordinance (IEO).

Customs earlier conducted a joint operation with the relevant department and raided two premises of the medical diagnostic group located in Yau Ma Tei and Kwun Tong. After investigation, Customs officers yesterday arrested a 61-year-old man and a 44-year-old woman.

Investigation is ongoing and the arrested persons have been released on bail pending further investigation.

Under the IEO, import and export of pharmaceutical products not under and in accordance with a licence is an offence. The maximum penalty upon conviction is a fine of $500,000 and imprisonment for two years.

Members of the public may report any suspected violations of the IEO to Customs' 24-hour hotline 2545 6182 or its dedicated crime-reporting email account (crimereport@customs.gov.hk).

Ends/Wednesday, June 5, 2019
Issued at HKT 14:52

NNNN

Annex 2

Joint operation by Hong Kong Customs and Department of Health to combat counterfeit vaccines (with photos)
****

Hong Kong Customs and the Department of Health (DH) conducted a joint operation and raided a medical centre in Kwun Tong on July 10. A total of 76 boxes of suspected counterfeit vaccines and 47 boxes of vaccines containing Part I poison with an estimated market value of about $280,000 in total were seized.

The DH earlier received a complaint alleging the use of a suspected problematic human papillomavirus (HPV) vaccine by a medical centre, which may also involve counterfeit products. After receiving the DH's referral, Customs conducted a preliminary investigation with the assistance of the trademark owner. Officers from Customs and the DH conducted joint enforcement action on July 10 and raided a medical centre located at a commercial building in Kwun Tong where the batch of suspected counterfeit vaccines and vaccines containing Part I poison were seized.

A 49-year-old male director and a 33-year-old male staff member of the medical centre were arrested.

Investigations by Customs and the DH are ongoing.

The Head of the Intellectual Property Investigation Bureau of the Customs and Excise Department, Mr Kwan Kin-keung, and the Chief Pharmacist of the DH, Mr Lot Chan, said at a press conference today (July 12) that Customs and the DH will continue to step up enforcement to combat counterfeit vaccines.

Customs reminds consumers to select reputable medical centres with care and verify with the trademark owners or their authorised agents if the authenticity of a vaccine is in doubt. Customs also reminds medical centres to be cautious and prudent in merchandising of vaccines since the possession of counterfeit goods for any trade or business is a serious crime and offenders are liable to criminal sanctions.

The DH urged members of the public who have felt unwell after receiving HPV vaccines to seek advice from healthcare professionals. According to the recommendation of the World Health Organization, the primary target group for cervical cancer vaccination is young women aged 9 to 14 years prior to becoming sexually active. Members of the public who have doubt on whether they should vaccinate or receive booster vaccines are advised to consult healthcare professionals. In addition, registered healthcare professionals should only procure registered pharmaceutical products from licensed wholesale dealers.

Under the Trade Descriptions Ordinance, any person who sells or possesses for sale any goods with a forged trademark commits an offence. The maximum penalty upon conviction is a fine of $500,000 and imprisonment for five years.

Under the Pharmacy and Poisons Ordinance, any person who possesses any poison included in Part 1 of the Poisons List other than in accordance with provisions commits an offence. The maximum penalty upon conviction is a fine of $100,000 and imprisonment for two years.

Ends/Friday, July 12, 2019
Issued at HKT 20:10

NNNN

Hong Kong Customs and the Department of Health conducted a joint operation and raided a medical centre in Kwun Tong on July 10. A total of 76 boxes of suspected counterfeit vaccines and 47 boxes of vaccines containing Part I poison with an estimated market value of about $280,000 in total were seized.

Hong Kong Customs and the Department of Health conducted a joint operation and raided a medical centre in Kwun Tong on July 10. A total of 76 boxes of suspected counterfeit vaccines and 47 boxes of vaccines containing Part I poison with an estimated market value of about $280,000 in total were seized. Photo shows the difference between the packaging of a suspected counterfeit vaccine (bottom) and a genuine vaccine (top).

Annex 3

Hong Kong Customs and Department of Health continue joint operation to combat counterfeit vaccines (with photo)
****

Hong Kong Customs and the Department of Health (DH) conducted a joint operation and raided a medical centre in Tsim Sha Tsui on July 12. A total of 162 boxes of suspected counterfeit vaccines and 163 boxes of vaccines containing Part 1 poison with an estimated market value of about $750,000 in total were seized.

The DH earlier received a complaint alleging the use of a suspected problematic human papillomavirus (HPV) vaccine by a medical centre and conducted a joint investigation with Customs. After preliminary investigation with the assistance of the trademark owner, officers from Customs and the DH conducted joint enforcement action on July 12 and raided a medical centre located at a commercial building in Tsim Sha Tsui where the suspected counterfeit vaccines and vaccines containing Part 1 poison were seized. Samples of the vaccines will be sent to the Government Laboratory for analysis.

A 35-year-old female director and two female staff members of the medical centre, aged 27 and 30, were arrested.

Investigations by Customs and the DH are ongoing.

Customs reminds consumers to select reputable medical centres with care and verify with the trademark owners or their authorised agents if the authenticity of a vaccine is in doubt. Customs also reminds registered healthcare professionals to be cautious and prudent in merchandising of vaccines since the possession of counterfeit goods for any trade or business is a serious crime and offenders are liable to criminal sanctions.

The DH urged members of the public who have felt unwell after receiving HPV vaccines to seek advice from healthcare professionals. According to the recommendation of the World Health Organization, the primary target group for cervical cancer vaccination is young women aged 9 to 14 years prior to becoming sexually active. Members of the public who have doubts on whether they should vaccinate or receive booster vaccines are advised to consult healthcare professionals. In addition, registered healthcare professionals should only procure registered pharmaceutical products from licensed wholesale dealers.

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Under the Pharmacy and Poisons Ordinance, any person who possesses any poison included in Part 1 of the Poisons List other than in accordance with provisions commits an offence. The maximum penalty upon conviction is a fine of $100,000 and imprisonment for two years.

Ends/Monday, July 15, 2019
Issued at HKT 19:39

NNNN

Hong Kong Customs and the Department of Health conducted a joint operation and raided a medical centre in Tsim Sha Tsui on July 12. A total of 162 boxes of suspected counterfeit vaccines and 163 boxes of vaccines containing Part 1 poison with an estimated market value of about $750,000 in total were seized. Photo shows some of the suspected counterfeit vaccines and vaccines containing Part 1 poison seized.

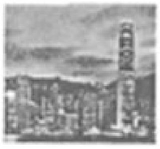
Annex 4

附件 4

2020年10月19日 16:02 HKT 27 65%

消費者委員會
CONSUMER COUNCIL

精明消費 香港遊



涉及售賣偽冒藥物店舖資料（2020年2月至5月審理完結的案件）
涉及售賣偽冒藥物店舖資料（2019年12月和2020年1月審理完結的案件）
全城抗疫 個人家居衞生必讀貼士
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Vaccination for the Right Time, the Right Dose, and the Right Recipient

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Introduction

The word "vaccine" originates from the Latin words "*variolae vaccinae*", which originally mean the cowpox. The ground breaking concept was introduced by a renowned scientist, Dr. Edward Jenner in the late 18th century, who practised a safe and efficacious means of preventing a deadly infectious disease, the smallpox, by using the pus of a patient previously infected with the cowpox that was less harmful.

"Vaccines" work by stimulating the human immune system to fight against the infectious diseases or cancers that could be caused by viruses, bacteria, or other agents. Vaccines have been one of the biggest success stories in modern medicine. The World Health Organization (WHO) estimates that at least 10 million deaths were prevented between 2010 and 2015 thanks to vaccinations delivered around the world. And, vaccines have been proven their values in defending against deadly, but once widespread, diseases, such as smallpox, tuberculosis, diphtheria, tetanus, and pertussis.

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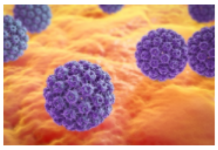
Examples of Vaccines

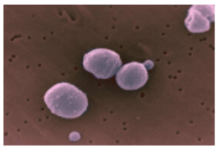
Common examples of the vaccines in Hong Kong include:

Viral



- Hepatitis A Vaccine
- Hepatitis B Vaccine
- Human Papillomavirus (HPV) Vaccine
- Japanese Encephalitis (JE) Vaccine
- Measles, Mumps and Rubella (MMR) Vaccine
- Rotavirus Vaccine
- Seasonal Influenza Vaccine (SIV)
- Varicella Vaccine

Bacterial



- Bacillus Calmette-Guérin (BCG) Vaccine
- *Haemophilus influenzae* type b (Hib) Vaccine
- Meningococcal Vaccine
- Pneumococcal Vaccine

Combined

- Diphtheria, Tetanus, acellular Pertussis and Inactivated Poliovirus (DTaP-IPV) Vaccine

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Schedules (The Right Time)

Vaccine protects our body by stimulating our immune system to prepare for the "real" infection that might happen in our life. Starting from the age of newborn, individuals can be vaccinated in accordance with established schedules.

For examples, under the Hong Kong Childhood Immunisation Programme, a newborn baby will be given with the BCG Vaccine, and also a first dose of the Hepatitis B Vaccine; while at the age of 1 month, the baby will receive a second dose of the Hepatitis B Vaccine. For Diphtheria, Tetanus, acellular Pertussis and Inactivated Poliovirus (DTaP-IPV) Vaccine, babies at the age of 2 months, 4 months, and 6 months will be given with the first, second and third dose of the vaccination respectively.

As for the Seasonal Influenza Vaccine (SIV), individuals from the age of 6 months onwards can be inoculated. Since the strains of influenza viruses that prevail in the community may change from time to time, the SIV needs to be received every year. You are advised to receive vaccination at least two weeks before the flu season each year; because it takes time for our body to build up the relevant antibodies.

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The Right Dose

Some vaccines only require one single dose to provide life-long protection. Nevertheless, most vaccines will require more than one dose (i.e. with the second dose, or third dose, several months apart). In addition to the above mentioned primary course of "multiple doses", some vaccines may even require the recipient to receive a "booster dose" after a fixed period (e.g. one year, or several years after). Different vaccines will have their own dosing; please consult the healthcare professionals for advice.

Vaccines usually come as injections; but some other forms (such as oral form and nasal spray) are also available. The vaccination doses are generally tiny. For the injection form (intramuscular or subcutaneous), the amount is usually about 0.5 millilitre (mL); for the oral vaccine, it could be more than 1 mL; for the nasal spray, the amount is about 0.1mL for each nostril. Other amounts of doses are possible for some other vaccines, depending on the way of administration, and the age of the recipient. For example, when BCG Vaccine is given to a newborn baby, the amount of dose could be as low as 0.05mL for intradermal injection. Healthcare professionals shall refer to the product insert for the recommended dose for the individual age group.

It is important to complete the whole course of vaccination. If a dose is missed, you should visit your doctor as soon as possible for professional advice.

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The Right Recipient

The vaccine products will have their own indication; and specific target population. For examples, the HPV vaccine is targeted at active immunization for individuals against cervical, vulvar, vaginal, anal lesions and cancers, which are related to persistent HPV infection. Individuals as early as the 9 years of age can receive the HPV vaccination.

For the SIV, babies as early as 6 months of age could be vaccinated; and people with a higher risk of influenza infection and its complications, such as the elderly, children, pregnant women, patients with chronic illness (such as the heart, lung, kidney disease, metabolic disease and immune insufficiency), and obese persons (who are too heavy with Body Mass Index (BMI) value ≥ 30) are especially encouraged to receive the SIV for personal protection. Residents of old age homes, and those living in care homes for the disabled also need the SIV. Apart from these, healthcare workers, poultry workers, pig farmers and other people who have a higher risk of contracting influenza should get vaccinated to ensure early protection.

For those who are suitable for the vaccinations, they should receive the vaccines in a timely manner, and according to the schedules. Under the Hong Kong Childhood Immunization Programme, children will receive different vaccines at specific ages according to the recommended schedules. For travellers planning to go abroad to high risk areas which require vaccination, you are advised to visit the website of the Travel Health Service before having your itinerary.

Not everyone is suitable for each kind of vaccine. It should be evaluated by a registered doctor before any vaccine is given. Some people (although the chance is rare) may be hypersensitive (e.g. symptoms of hives, wheezing, etc.) to a particular vaccine; rendering them not suitable for that vaccination.

Healthcare providers will ask vaccine recipients on their medical history, and whether hypersensitivity to vaccines has happened; they will evaluate the health condition before deciding whether to give the vaccine, or continue the vaccination schedule.

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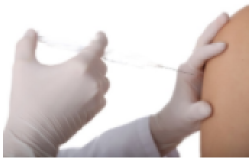
Some Common Side Effects of Vaccines

Vaccines can trigger immune response and they may cause some side effects. After vaccination, healthcare providers usually advise the recipient to stay for a while (e.g. 15 minutes to half an hour); in case any acute hypersensitivity happens, immediate treatment could be provided.



The side effects of vaccines are usually mild and transient; and will subside in a few days. The common side effect includes pain (and sometimes redness, swelling and hardening) at the injection site. The recipient may also feel tired, or have muscle pain. Some individuals may have fever, and headache, etc. Oral vaccines may cause gastrointestinal discomfort (such as diarrhea). Each vaccine will have its own side effect profile. If the side effect persists, or worsens after a few days, seek medical consultation.

Severe adverse effect (e.g. swollen mouth and tongue, difficulty in breathing, or paralysis) warrants immediate medical attention.

In general, vaccines are safe and their efficacy and quality have to be proven before they could be marketed.

Information about childhood immunization is available at the Family Health Service of the Department of Health. To understand more about communicable diseases, please visit the website of the Centre for Health Protection.

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Stability and Storage for Vaccines

Vaccines should be stored under conditions as recommended by the manufacturers. Each vaccine has its specific shelf-life and storage requirements, which will be displayed on the label. Usually vaccines need to be stored between 2ºC and 8ºC; and away from light. The storage conditions (such as temperature) should be closely monitored and recorded. Storage outside the recommended conditions may affect the quality and potency of the vaccine; and may render it not usable. Although the vaccine should usually be stored at 2ºC ~ 8ºC, it could nevertheless stay at room temperature for a short while immediately before the vaccination.

Most vaccine products should not be frozen. Any frozen vaccines (contrary to the storage instruction) have to be discarded.

Prior to use, the vaccine should be inspected for any irregularities or foreign matters. If in doubt, the vaccines should not be used.

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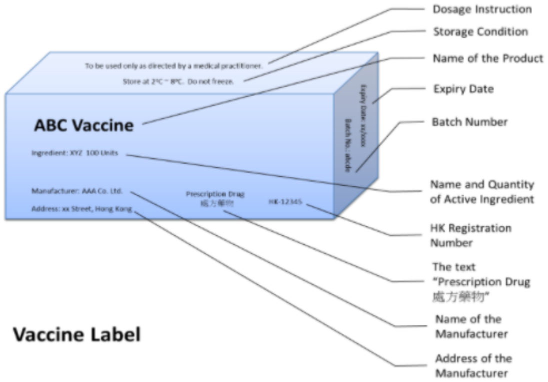
Legal Aspects of Vaccines

Vaccines are prescription-only medicines; and like any other pharmaceutical products, vaccines must be registered by the Pharmacy and Poisons Board of Hong Kong, before they can be sold, or distributed locally in Hong Kong. Importer/exporter of pharmaceutical products must be holder of a wholesale dealer licence issued under the Pharmacy and Poisons Ordinance (Cap. 138) and a valid import/export licence is required for every shipment of the pharmaceutical to be imported or exported.

For all registered pharmaceutical products, the outermost package (label) must display a Hong Kong Registration Number (i.e. HK-XXXXX (five numbers)). In addition, the label should also have the product name, the name of the active ingredient and its quantity, the name and address of the manufacturer, the batch number, and the expiry date. For prescription-only medicine, the label should have the text "Prescription Drug 處方藥物" in both English and Chinese **(Figure)**.



For sterile products, the label on the vial or syringe of the vaccine should also contain the batch number and the expiry date; and, if applicable, the name of the preservative.

Any specific storage instruction of the vaccine (e.g. Store at 2ºC ~ 8ºC; Do not freeze) should also be displayed clearly on the label.

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Checking the Registration Status of a Pharmaceutical Product

Information on all registered pharmaceutical products is available from the Drug Office's website (http://www.drugoffice.gov.hk):

(1) You can search information on a particular pharmaceutical product by entering the particulars of the pharmaceutical product (such as its product name or name of the active ingredient in English, or its Hong Kong Registration Number) in the "Search Drug Database" function
http://www.drugoffice.gov.hk/eps/do/en/consumer/search_drug_database.html

(2) You may also get information of all pharmaceutical products in alphabetical order by viewing the web version of the Compendium of Pharmaceutical Products
http://www.drugoffice.gov.hk/eps/do/en/doc/Compdium.pdf

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Tips on Differentiating a Registered Product

As mentioned above, the box or the label of a vaccine should contain a Hong Kong registration number as well as "Prescription Drug 處方藥物". If this specific information is not found on the outer box of the vaccine, it is probable that the product is not registered in Hong Kong.

Under the existing legislation, the name of the pharmaceutical product and its active ingredients are registered in English. Therefore, the product name and the active ingredient name in English will be displayed on the outer box, some products may also have Chinese product names in additional to the English names. And, other information, e.g. usage instructions, warnings, can be displayed in English and/or in Chinese. Occasionally, there may be statements in a third language in addition to English and Chinese, e.g. some European languages for products destined to some European countries. However, if you notice the outer box of a vaccine "only" contains foreign languages or "only" in Chinese, whether simplified or traditional Chinese, it is probable that the product is also not registered in Hong Kong. Some examples may include: the outer box only labelled in Japanese; or the product only contains simplified or traditional Chinese without a product name in English.

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Consumers' Rights

Vaccines are prescription drugs. Consumers will usually receive vaccination at the premises where registered doctors practice their profession (for examples, hospitals, clinics, private consulting rooms). Vaccination needs to be performed by and under the supervision of registered doctors. Before receiving vaccination, consumers can look up whether the responsible person is a doctor that is registered in Hong Kong. For the list of registered doctors, please visit the website of "The Medical Council of Hong Kong".
https://www.mchk.org.hk/english/list_register/index.html

Where necessary, citizens can ask for viewing the vaccines; check for the five digits "Drug Registration Number (HK-XXXXX)" on the label of the vaccine product; and see whether the necessary information is on the outermost package of the product before the healthcare workers perform the vaccination. If suspecting that a product is not registered in Hong Kong, you check with or report to the Drug Office of the Department of Health (Tel.: +852-2572-2068; email: pharmgeneral@dh.gov.hk).

You can also contact the Registration Certificate Holder of the product, as to how to distinguish product authenticity. Consumers can compare the anti-counterfeiting features of the products, and check for the details such as batch number and expiry date. In cases of doubt, you can contact the Hong Kong Association of the Pharmaceutical Industry for enquiry (Tel.: +852-2528-3061; email: info@hkapi.hk). If you want to report a counterfeit product, please contact direct the Custom and Excise Department of Hong Kong (Tel.: +852-2815-7711; email: customsenquiry@customs.gov.hk).

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Summing Up

Vaccines are manufactured with stringent quality control; and require due attention to temperature during storage and during transportation. They are prescription-only medicines. Although vaccines may cause side effects, they help us to develop immunity against the disease-causing agent. With better understanding of the vaccines and with proper use, the vaccines are valuable tools to protect public health.

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Drug Office
Department of Health
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